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EXAMINER

MILLER, MARINA I

ART UNIT PAPER NUMBER

1631

DATE MAILED: 09/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/807,811

Applicant(s)

SCOTT, IAN R.

Examiner

Marina Miller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-48 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-27, drawn to a method for identifying highly synergistic combinations of biologically active agents, classified in class 424, subclass 9.2 or class 514, subclass 1+ (depending on the agent).
- II. Claims 28-39, drawn to a highly synergistic combination of biologically active agents, classified in class 514, subclass 1+; class 424, subclass 9.2, 70.1 (depending on the agent).
- III. Claims 40-41, drawn to a method for identifying agents displaying maximum biological activity in hair growth testing hair follicles, classified in class 424, subclass 9.2; 70.1; class 514, subclass 1+ (depending on the agent).
- IV. Claims 42-43, drawn to a method for identifying agents displaying maximum biological activity in hair growth testing whole skin, classified in class 424, subclass 9.2; class 514, subclass 1+ (depending on the agent).
- V. Claim 44-45, drawn to a method for identifying agents displaying maximum biological activity in skin aging testing in histology organ culture assay, classified in class 424, subclass 9.2; class 514, subclass 1+ (depending on the agent).
- VI. Claim 46, drawn to a method for identifying agents displaying maximum biological activity in controlling acne testing in the simulated follicle P, classified in class 424, subclass 9.2; class 514, subclass 1+ (depending on the agent).

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- VII. Claim 47, drawn to a method for identifying agents displaying maximum biological activity in controlling acne testing in the IL1 assay, classified in class 424, subclass 9.2; 85.2.
- VIII. Claim 48, drawn to a method for identifying agents displaying maximum biological activity in controlling dental plaque, classified in class 424, subclass 9.2; 49; class 514, subclass 1+ (depending on the agent).

The inventions are distinct, each from the other because of the following reasons:

Inventions I and III-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06).

In the instant case, each method has a different goal and/or method steps, and therefore has different effects and modes of operation. For example, the method of Invention I is directed to identifying highly synergistic combinations of biologically active agents comprising steps of selecting a library of compounds and identifying multiple subsets of mixtures displaying synergy in a multi-pathway high throughput assay. The method of Invention IV is directed to identifying agents displaying maximum biological activity in hair growth testing hair follicles. The method of Invention V is directed to identifying agents displaying maximum biological activity in hair growth testing whole skin in a culture assay. The method of Invention VI is directed to identifying agents displaying maximum biological activity in skin aging testing in histology organ culture assay. The method of Invention VII is directed to identifying agents displaying maximum biological activity in controlling acne testing in the simulated follicle P. The method of Invention VIII is directed to identifying agents displaying maximum biological activity in

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controlling acne testing in the IL1 assay. The method of Invention VIII is directed to identifying agents displaying maximum biological activity in controlling dental plaque. Thus, each method has different effect. Also, each method comprises steps requiring manipulations that are not required for any other method, and therefore each method has different mode of operation and design.

Inventions I and II are related but distinct. The related inventions are distinct if the inventions as claimed do not overlap in scope, *i.e.*, are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the method of Inventions I and the composition of Invention II are related but distinct. The method of Invention I merely identifies the composition, which can be identified by a method different from the method of Invention I, *e.g.*, using specific assays such as an enzyme inhibition (*see* the specification p. 4). Also, the method of Invention I is capable of identifying different compositions providing different specific biological effects (*see* claims 33-39). Thus, Inventions I and II are not required one for the other and have different effects and mode of operation.

Inventions II and III-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06).

In the instant case, the different methods of Inventions III-IV do not use or make the highly synergistic composition of Invention II, but merely identify agents that display maximum

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biological activity using various assays. Therefore, Inventions II and III-VIII are not capable to be used together, and also have different mode of operation, design, and effect.

Because these Inventions are distinct for the reasons given above, the classification is different, and the non-patent and patent literature search required for each group is not coextensive with that requirement for another group, restriction for examination purposes as indicated is proper.

Species Election

This application contains claims directed to the following patentably distinct species:

Species A: select one library of potential activities among those recited, for example, in claims 3-5.

Species B: select one source of “actives” among those recited, for example, in claim 6.

Species C: elect one multi-pathway high throughput assay among those recited in claims 7, 12, 15, 18, 20-23, 29, and 33-39.

Species D: elect one highly synergistic combination among those recited, for example, in claims 29 and 33-39.

i) If applicants elect a biological end effect of hair growth as recited in claim 7, applicants are further required to elect one assay among the isolated hair follicle assay and the low temperature whole skin organ culture assay recited in claims 8 and 10;

ii) If applicants elect the biological effect of skin anti-aging as recited in claim 12, applicants are further required to elect one assay among the high throughput histological organ culture assay and the topical application high throughput histological organ culture assay recited in claims 13-14;

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iii) If applicants elect the resolution or prevention of acne as recited in claim 15, applicants are further required to elect one assay among the simulated follicle P acnes assay and the inhibition of IL1- induced hypercornification assay recited in claims 16-17.

The species are independent or distinct because:

Species A, different libraries of activities, are distinct because they are independent, have different structure, and are not required one for the other. Data generated for one library of activities is expected to be different from the data generated for any other library.

Species B, different activities, are distinct because they are independent, have different structure and function, and generally discloses in different literature. Data generated for one activity is expected to be different from the data generated for any other activity.

Species C, different assays, are distinct because they are independent, not required one for the other, and data generated from one assay is expected to be different from the data generated from any other assay.

Species D, different highly synergistic combinations, are distinct because they have different structure and function, affect different biological activities, and data generated for one combination is expected to be different from the data generated for any other combination.

Applicant is required under 35 U.S.C. 121 to elect ONE species from EACH of Species A-D above and required sub-species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Currently, 1-2, 24-28, and 40-48 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Miller whose telephone number is (571)272-6101. The examiner can normally be reached on 8-6, M-Thu.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, Ph. D. can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marina Miller
Examiner
Art Unit 1631

MARJORIE A. MORAN
PRIMARY EXAMINER

Marjorie A. Moran
8/31/06

MM